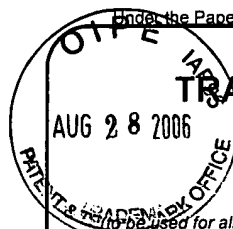


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TRANSMITTAL
FORM

(To be used for all correspondence after initial filing)

Total Number of Pages in This Submission

12

Application Number

09/614,790

Filing Date

July 12, 2000

First Named Inventor

Sharon F. Kleyne

Art Unit

1617

Examiner Name

Wang, Shengjun

Attorney Docket Number

HME/7982.0001

ENCLOSURES (Check all that apply)



Fee Transmittal Form



Fee Attached



Amendment/Reply



After Final



Affidavits/declaration(s)



Extension of Time Request



Express Abandonment Request



Information Disclosure Statement



Certified Copy of Priority Document(s)

Reply to Missing Parts/
Incomplete ApplicationReply to Missing Parts
under 37 CFR 1.52 or 1.53

Drawing(s)



Licensing-related Papers



Petition

Petition to Convert to a
Provisional ApplicationPower of Attorney, Revocation
Change of Correspondence Address

Terminal Disclaimer



Request for Refund



CD, Number of CD(s) _____



Landscape Table on CD



After Allowance Communication to TC

Appeal Communication to Board
of Appeals and InterferencesAppeal Communication to TC
(Appeal Notice, Brief, Reply Brief)

Proprietary Information



Status Letter

Other Enclosure(s) (please identify
below):

Remarks

Reply Brief - 10 pages

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name

Howard Eisenberg, Esq.

Signature

Printed name

Howard Eisenberg

Date

August 24, 2006

Reg. No.

36,789

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

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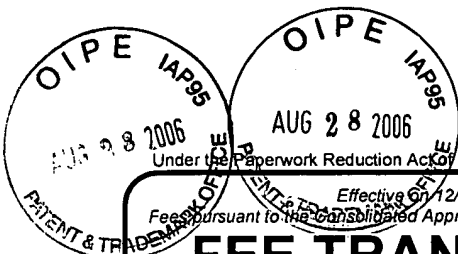
Howard Eisenberg

Date

August 24, 2006

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Effective 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).**FEE TRANSMITTAL**
For FY 2005☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 0

Complete if Known

| | |
|----------------------|------------------|
| Application Number | 09/614,790 |
| Filing Date | July 12, 2000 |
| First Named Inventor | Sharon F. Kleyne |
| Examiner Name | Wang, Shengjun |
| Art Unit | 1617 |
| Attorney Docket No. | HME/7982.001 |

METHOD OF PAYMENT (check all that apply)☐ Check ☐ Credit Card ☐ Money Order ☒ None ☐ Other (please identify): _____☐ Deposit Account Deposit Account Number: 50-1773 Deposit Account Name: Howard Eisenberg

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

FEE CALCULATION**1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

| Application Type | FILING FEES | | SEARCH FEES | | EXAMINATION FEES | | Fees Paid (\$) |
|------------------|-------------|-----------------------|-------------|-----------------------|------------------|-----------------------|----------------|
| | Fee (\$) | Small Entity Fee (\$) | Fee (\$) | Small Entity Fee (\$) | Fee (\$) | Small Entity Fee (\$) | |
| Utility | 300 | 150 | 500 | 250 | 200 | 100 | |
| Design | 200 | 100 | 100 | 50 | 130 | 65 | |
| Plant | 200 | 100 | 300 | 150 | 160 | 80 | |
| Reissue | 300 | 150 | 500 | 250 | 600 | 300 | |
| Provisional | 200 | 100 | 0 | 0 | 0 | 0 | |

2. EXCESS CLAIM FEES**Fee Description**

Each claim over 20 (including Reissues)

| Fee (\$) | Small Entity Fee (\$) |
|----------|-----------------------|
| 50 | 25 |

Each independent claim over 3 (including Reissues)

| | |
|-----|-----|
| 200 | 100 |
|-----|-----|

Multiple dependent claims

| | |
|-----|-----|
| 360 | 180 |
|-----|-----|

| Total Claims | Extra Claims | Fee (\$) | Fee Paid (\$) |
|----------------|--------------|----------|---------------|
| 9 - 20 or 43 = | 0 | 25 | 0 |

HP = highest number of total claims paid for, if greater than 20.

| Indep. Claims | Extra Claims | Fee (\$) | Fee Paid (\$) |
|---------------|--------------|----------|---------------|
| 1 - 3 or 5 = | 0 | 100 | 0 |

HP = highest number of independent claims paid for, if greater than 3.

| Multiple Dependent Claims | Fee (\$) | Fee Paid (\$) |
|---------------------------|----------|---------------|
| | | |

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

| Total Sheets | Extra Sheets | Number of each additional 50 or fraction thereof | Fee (\$) | Fee Paid (\$) |
|--------------|--------------|--|----------|---------------|
| | | | | |

- 100 = / 50 = (round up to a whole number) x =

4. OTHER FEE(S)

Non-English Specification, \$130 fee (no small entity discount)

Other (e.g., late filing surcharge): _____

Fees Paid (\$)**SUBMITTED BY**

| | | | |
|-------------------|------------------|--|--------------------------|
| Signature | | Registration No. (Attorney/Agent) 36,789 | Telephone (215) 453-9237 |
| Name (Print/Type) | Howard Eisenberg | Date August 24, 2006 | |

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Atty Doc. No. HME/7982.001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT APPLICATION EXAMINING OPERATIONS

In re the Application of :
Sharon F. Kleyne : Group Art Unit: 1617

Serial No. 09/614,790 : Examiner: Shengjun Wang

Filed: July 12, 2000 : Tel. No. (571) 272-0632

For a Patent for : Date: August 24, 2006
METHOD AND KIT FOR MOISTURIZING
THE SURFACE OF THE EYE

**APPELLANT'S REPLY BRIEF TO EXAMINER'S ANSWER
UNDER PART 41 OF TITLE 37 C.F.R., §41.41**

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir,

In response to the Examiner's Answer mailed on July 25, 2006 to Appellant's Brief filed on April 7, 2006, Appellant submits this Reply Brief, in accordance with Part 41 of Title 37 C.F.R., §41.41.

The following numbers relate to the numbering of the sections in the Examiner's Answer.

1 to 8. No response to the Examiner's Answer is necessary.

9. Grounds of Rejection

The Examiner has rejected the pending claims on the ground of obviousness over the combined disclosures of Junkel, U.S. Patent No. 5,620,633; Hahn, U.S. Patent No. 5,893,515; Hutson, U.S. Patent No. 5,588,564; and Embleton, WO 97/23177.

As stated by the Examiner in the Examiner's Answer, Junkel discloses a portable misting device that provides a cooling current of air with atomized liquid mist, such as water. Junkel discloses that the mist is directed toward the body of a sunbather or of one engaged in athletic pursuits, so as to cool the body of that individual. The Examiner has admitted that Junkel does not disclose the use of the mist for the face and that there is no disclosure in Junkel of applying a mist to the eyes.

Rather, the Examiner states, without support, that it is obvious to anyone who experiences a dry condition, i.e. dry eye, to apply a water mist and moisturize the eye to relieve the dryness. To support this contention, the Examiner further cites Hahn and Hutson, each of which discloses a device for producing a mist for application to the eyes.

However, neither Hahn nor Hutson disclose the use of "water" for moisturizing the eye. Rather, Hahn refers to a liquid medium, comfort liquids, or eye drop liquids, and Hutson refers to a fluid, an eye wash solution, or an eye solution mist. Appellant has previously submitted a Declaration of Dr. Rachael Garrett on January 9, 2002 (see Appeal Brief, Evidence Appendix IX, No. 1), who provides testimony that fluids such as artificial tears, dry eye therapies, and comfort drops contain ingredients other than water that are essential for their beneficial effects. Thus, it clear that the liquids disclosed in Hahn and Hutson are other than "water."

Further, Appellant has previously submitted a Declaration of Dr. Philip Paden (see Appeal Brief, Evidence Appendix IX, No. 2) that provides testimony that it has been a long-accepted doctrine in the field of ophthalmology that administration of water to the eye is not a suitable therapy because of the reduction of osmolarity on the surface of the eye with resultant deleterious effects. Thus, contrary to the Examiner's contention, Appellant respectfully submits that it is not obvious to apply water to the eye in order to moisturize the eyes or to relieve the discomfort of dry eyes. As testified by Dr. Paden, the present invention overcomes this problem by administering the water in the form of tiny droplets which do not wash away the tear film but rather become incorporated into it. In this way, and in contrast to what those in the art would understand to be the effect of water administration to the eye, with the method of the invention there is no decrease below normal osmolarity and no resultant deleterious effects.

The Examiner stated that the mist generated by the device of Junkel is not likely to wash away the tear film or the proteins and electrolytes in the tear film because the water is applied as a mist. Appellant submits that the Examiner's statement is without merit because the tendency of an administered fluid to wash away the tear film or the proteins and electrolytes in the tear film is not predicated solely on what form, such as a mist, that the fluid is administered. Rather, it is primarily related to the amount of fluid that is applied to the eye.

As disclosed in the specification on page 2, lines 26 to 33, a typical eye drop contains about 20 to 25 microliters of fluid, and this amount of fluid is sufficient to flood the eye, which washes away the tear film and replaces the tear film with the fluid that comprises the eye drop. There is no disclosure or suggestion in Junkel to administer an amount of fluid to the eye less than that which will flood the eye and wash away the tear film.

The secondary reference Hahn discloses administering an amount of fluid that is sufficient “to saturate the eye without overflowing - about one drop.” As disclosed in the present specification, this one drop of Hahn that saturates the eye (even if there is no overflowing) is sufficient to flood the eye and to wash away the tear film and replace it with the fluid that is administered by Hahn. The secondary reference Hutson is silent as to the volume of liquid that is dispensed to the eye.

Thus, Appellant submits that the combination of Junkel, Hahn, and Hutson does not suggest the amount of liquid to be administered to the eye, as called for in the present claims, which amount provides advantageous not obtained with previous methods for moisturizing the eye.

The Examiner, however, further cited Embleton for its disclosure that liquid administered to the eye should be less than 30 microliters as over-administration of liquid to the eye provides no benefit. Pending claims 98 to 100 call for particular amounts of fluid less than 30 microliters. Appellant submits, however, that Embleton is not pertinent to the present invention.

Embleton is concerned with a problem that is different than that which is solved by the present invention. Embleton deals with the problem of administering treatment liquids to the eye, such as those containing drugs. If such a liquid is administered to the eye in an amount that will flood the eye, several bad things result. The first bad result is that providing a medicament in an amount of liquid that is greater than that which can be retained by the eye results in wastage of the medicament due to runoff from the eye. The second bad result is a lack of precision in dosage because one does not know how much of the over-administered medicament was actually retained in the eye and how much of the medicament was lost due to runoff from the eye. The third and

most serious deleterious defect of administering a treatment liquid to the eye in too large of a volume is that it results in drainage of the medicament down the tear duct and into the nasal passages from where it can be inhaled into the systemic circulation of a patient, with potentially disastrous effects depending on the nature of the medicament. As a solution to this problem, and not to the problem of moisturizing the eye, Embleton discloses an apparatus that targets a treatment liquid in the form of a jet or a stream to the surface of the eye and which delivers a small volume of a treatment fluid so as not to flood the eye and cause runoff.

Appellant further submits that it is improper to cite Embleton against the present invention because Embleton teaches away from the present invention. Embleton discloses that the treatment liquid is directed to the eye in the form of a jet or stream. Such a jet or stream is necessary to the invention of Embleton because Embleton is concerned with targeting a treatment liquid, such as a drug, to the eye. The mist of the present invention would not be suitable for the invention of Embleton because providing a treatment liquid, such as a drug, in the form of a mist would result in a great portion of the drug missing the eyes and landing elsewhere on the face or being lost in the air.

For these reasons, and for the reasons submitted in Appellant's Brief, Appellant submits that the Examiner has failed to establish prima facie obviousness of the claims in view of the cited prior art.

10. Response to Argument

The Examiner implied in the Answer that Appellant has argued against the references individually, rather than on the combination of the references. Appellant submits that

the arguments of Appellant are directed to the combined disclosures of the references and it is clear that the combined disclosure is insufficient to establish prima facie obviousness of the claims.

The Examiner stated that there is motivation to combine the cited references as well as the knowledge generally available in the art. The Examiner stated that moisturizing a body part for relieving dryness is within knowledge generally available. However, this statement does not provide a motivation to combine the references cited by the Examiner, which references deal with very different matters.

Junkel is concerned with applying a mist to the body (trunk and appendages). There is no disclosure or suggestion in Junkel concerning the eyes. Hahn and Hutson are concerned with applying a mist to the eyes. Embleton is concerned with applying a jet or stream in order to target a medication to the eye.

Appellant submits that there is no suggestion in the references, or elsewhere, to combine these cited references. Appellant submits that the present situation has several similarities to the case in *In re Rouffet*, 149 F.3d 1350, 1357, 47 U.S.P.Q.2d 1453, 1457-58 (Fed. Cir. 1998). In that case, the Federal Circuit reversed a finding of obviousness based on the fact that the Board had failed to establish a teaching, suggestion, or motivation to combine the references that had been cited against the patent application at issue.

In *In re Rouffet*, the court admitted that the combination of references cited contained all of the elements claimed in the Rouffet application. However, because the Board did not explain the specific understanding or principle within the knowledge of one skilled in the art that would motivate one with no knowledge of Rouffet's invention to make the combination, it

was clear to the court that the references were selected by the Examiner with the impermissible assistance of hindsight. Therefore, the finding of obviousness was reversed.

Similarly, in the present instance, the Examiner has merely stated that:

In this case, the teaching suggestion and motivation (for combining the references) is found in the cited references and in knowledge generally available to one in the art. Particularly, moisturizing a dry body part for relieving dryness is within the knowledge generally available to one of ordinary skill in the art. (parentheses added for clarity)

Appellant respectfully submits that the Examiner has failed to explain the specific understanding or principle within the knowledge of one skilled in the art that would motivate one with no knowledge of the presently claimed invention to make the combination of references cited by the Examiner. Therefore, the Examiner's selection of these references was impermissibly made with the assistance of hindsight. Accordingly, Appellant submits that the claims cannot properly be held to be unpatentable over the cited prior art references.

In his Answer, the Examiner further stated that the secondary evidence presented in the application is insufficient to rebut the prima facie case of obviousness.

First, the Examiner states that the Declarations are insufficient to overcome the rejection for obviousness because they testify to the recognition of a newly discovered advantage that would naturally flow from the suggestion of the prior art. However, it is submitted that the Examiner has incorrectly characterized the testimony of the Declarations.

Dr. Philip Paden, in his Declaration filed on January 21, 2004 (see Appeal Brief, Evidence Appendix IX, No. 2), testified that the use of water as a moisturizing agent for the eye represents a significant departure from previously accepted doctrines in the field of ophthalmology. Dr. William Mathers, in his Declaration filed on January 30, 2004 (see Appeal

Brief, Evidence Appendix IX, No. 5) testified that the claimed invention provided unexpected advantageous properties. Dr. Darwin Liao, in his Declaration filed on January 30, 2004 (see Appeal Brief, Evidence Appendix IX, No. 6) testified that the claimed invention provided unexpected advantageous properties. Dr. William Mathers, in his Second Declaration filed on May 10, 2005 (see Appeal Brief, Evidence Appendix IX, No. 7) testified that the invention addresses and solves a long-standing unresolved problem pertaining to the treatment of patients with symptoms due to dry eyes.

Appellant submits that these declarations testify to much more than merely the recognition of a newly discovered advantage that would naturally flow from the suggestion of the prior art. Rather, they testify that the present invention is a departure from previously accepted dogma in the art, that the invention solves a long-standing unresolved problem, and that the invention provides unexpected advantageous properties. Appellant submits that this testimony is sufficient to overcome a case of prima facie obviousness established by the Examiner. In this case, however, it is further submitted that the declarations are not necessary to determine that the present invention is patentable because the Examiner has failed to establish prima facie obviousness of the claims.

The Examiner further stated that the evidence provided by Appellant (see Appeal Brief, Evidence Appendix IX, No. 8) to establish commercial success of the invention is not commensurate with the scope of the claims. The Examiner stated that the alleged evidence of commercial success is about a device for providing mist whereas the invention is directed to a method for moisturizing the eye.

Appellant submits, however, that the Examiner is in error in his interpretation of this evidence. The article discloses that troops in Iraq and Kuwait spray their eyes with a product called "Nature's Tears" and they use this product by holding the eye mist 12 to 18 inches from their eyes and misting themselves. Thus, the article speaks to a method for moisturizing the eye, not merely a product.

Appellant submits that, for the above reasons and for the reasons provided in the Appeal Brief, the Examiner has failed to establish prima facie obviousness of the claims and that, if the Board finds that the Examiner has established prima facie obviousness of the claims, the evidence submitted by Appellant in the form of declarations and publication is sufficient to overcome the prima facie obviousness. It is submitted that Appellant has established that the claims are patentably distinct from the prior art and the Board is requested to rule accordingly.

11. No response to the Examiner's Answer is necessary.

Conclusion

For the above reasons and for those provided in the Appeal Brief, the Board is respectfully requested to reverse the Examiner's finding of obviousness of the claims.

Respectfully submitted,



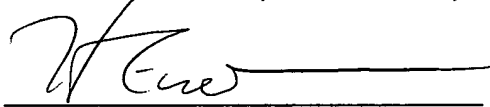
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CERTIFICATE OF MAILING

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Dated: _____

8/24/2006



Howard M. Eisenberg